IVAC® 597 Volumetric Pump

Directions For Use - English

CardinalHealth

CE 0086

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Introduction

The IVAC® 597 Volumetric Pump (hereinafter referred to as 'Pump') is a small lightweight volumetric infusion pump that provides accurate and reliable infusions over a range of rates.

The IVAC® 597 Volumetric Pump automatically regulates the infusion rate of intravenous solutions. The microprocessor-based pump uses a linear peristaltic, volume displacement mechanism to regulate fluid flow at the desired rate. The pump's many features include:

- Easy setup and operation:

  Advisory prompts to assist in setup and operation.

  Quick start mode.

  Diagnostic alarm messages to simplify operation and troubleshooting.

  Easy viewing of rate and volume-to-be-infused (VTBI) settings.
- Wide range of infusion rates: 1 to 999 ml/h in 1 ml/h increments.
- Volumetric rate entry.
- Volume-to-be-infused capability with automatic switchover to the "keep vein open" (KVO) rate.
- Integral ultrasonic air-in-line detection.
- Detection of upstream/downstream occlusions.
- Low occlusion pressures (nominal 6 to 8 psi).
- Lightweight and portable with self-contained rechargeable battery.
- Automatic flow shutoff with activation of audible and visible alarms.
- Audible and visible low battery alert about one hour before battery alarm.
- Optional flow sensor (Model 192).
- Optional remote computer monitoring capability.
- Secondary operation

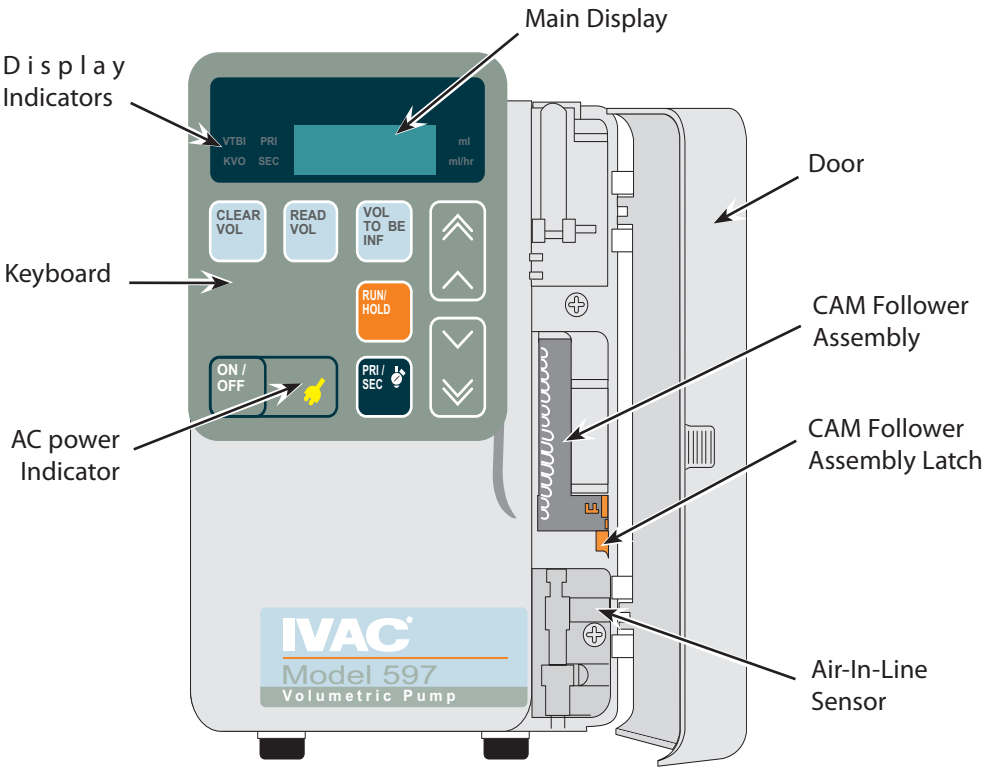
INTENDED USE:

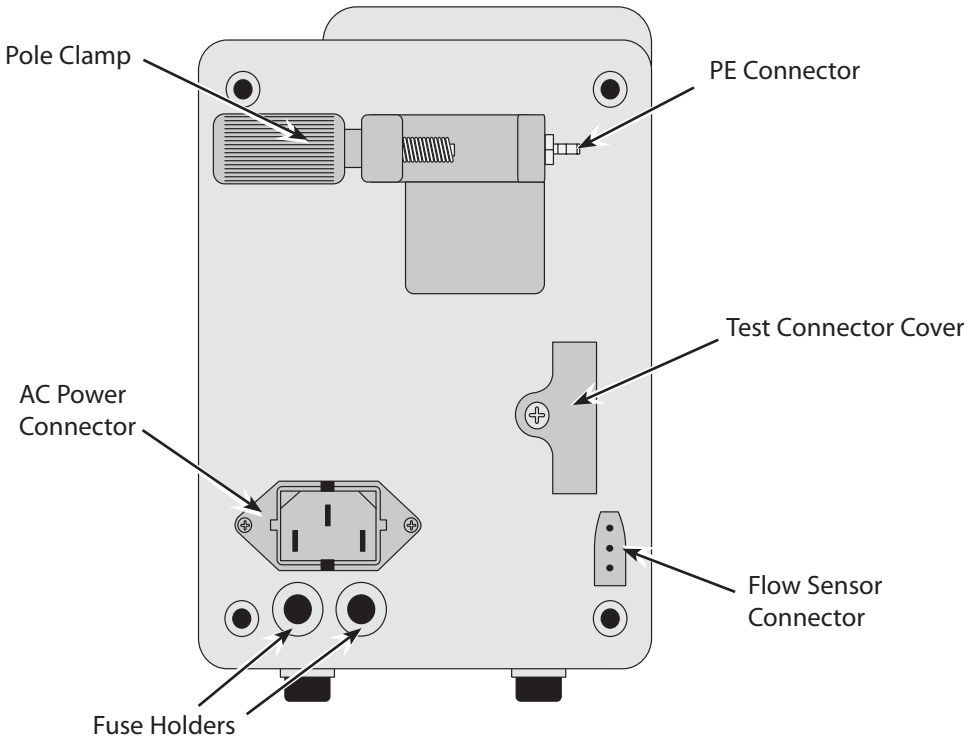
The pump is designed to meet the infusion requirements within the operating environment specified in this Directions For Use (DFU) including general wards, critical and intensive care, operating rooms and accident and emergency rooms.

This pump is suitable for use by appropriately trained clinicians or nurses. This pump can be used for Intravenous modes, supporting fluid therapy, drug therapy, blood transfusions and parenteral nutrition.

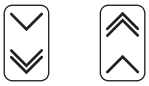
About this Manual

The user must be thoroughly familiar with the pump described in this manual prior to use.
All illustrations used in this manual show typical settings and values which may be used in setting up the functions of the pump.
These settings and values are for illustrative use only. The complete range of settings and values are detailed in the specifications section.


Main Display
Display Indicators
Door
Keyboard
CAM Follower Assembly
CAM Follower Assembly Latch
AC power Indicator
Air-In-Line Sensor
VTBI PRI
KVO SEC
ml
ml/hr
CLEAR VOL
READ VOL
VOL TO BE INF
RUN/ HOLD
ON / OFF
PRI / SEC
IVAC
Model 597
Volumetric Pump


Pole Clamp
PE Connector
Test Connector Cover
AC Power Connector
Flow Sensor Connector
Fuse Holders

Controls:

Symbol	Description
ON/ OFF	**ON/OFF** switch - Press once to switch the pump ON. Press and hold down for approximately 3 seconds to switch the pump OFF.
RUN/ HOLD	**RUN/HOLD** switch - Starts and stops pump infusions. Silences/cancels alarms.
VOL TO BE INF	**VOLUME TO BE INFUSED** switch - Sets value of Volume To Be Infused (VTBI).
CLEAR VOL	**CLEAR VOLUME** switch - Resets volume infused value to zero.
READ VOL	**READ VOLUME** switch - Displays volume infused value.
PRI SEC/	**PRIMARY/SECONDARY** switch - Switches the pump between PRIMARY and SECONDARY infusion modes.
	**CHEVRON** switches - Double chevrons/single chevrons for faster/slower increase or decrease of infusion rate and volume values.

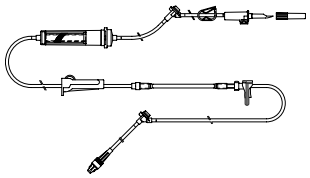
Indicators:

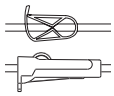
Symbol	Description
	**AC POWER** indicator - When illuminated the pump is connected to an AC power supply and the battery is being charged.
VTBI	The value displayed is the Volume To Be Infused.
KVO	The pump is infusing at the Keep Vein Open (KVO) rate of 5ml/h (or current rate, whichever is less).
ml	(Millilitres) The value displayed is the VTBI or volume infused value.
ml/hr	(Millilitres / hour) The value displayed is the infusion rate.
PRI	The pump is operating in PRIMARY mode.
SEC	The pump is operating in SECONDARY mode.
	Infusion indicator. Three horizontal bars in the left-hand display position flash sequentially when the pump is infusing.
	Infusion indicator with Flow Sensor in use. Upper two horizontal bars convert to a square when a drop is detected by the flow sensor in the drip chamber.
Flashing Display	When the pump is operating on battery power, the Display flashes on/off.

Labelling Symbols:

Symbol	Description
	Attention (Consult accompanying document)
	Potential Equalisation (PE) Connector
	Type CF applied part. (Degree of protection against electrical shock)
IPX1	Protected against vertically falling drops of water
CE 0086	Device complies with the requirements of the EC Directive 93/42/EEC. Registered with the CE Mark.
	Date of Manufacture
	Manufacturer
	Important Information
	Not for Municipal Waste
	Fuse rating

Operating Precautions





Infusion Sets

- To ensure correct and accurate operation, only use Cardinal Health single use infusion sets described in this Directions For Use.
- It is recommended that infusion sets are changed according to the instructions in the 'Changing the Infusion Set' section. Carefully read the Directions For Use supplied with the infusion set prior to use.
- Use of non-specified infusion sets may impair the operation of the pump and the accuracy of the infusion.
- When combining several apparatus and/or instruments with infusion sets and other tubing, for example via a 3-way tap or multiple infusion, the performance of the pump may be affected and should be monitored closely.
- Uncontrolled flow may result if the infusion set is not properly isolated from the patient i.e. closing a tap in the set or activating an in-line clamp / roller clamp.
- The infusion set may be fitted with an in-line clamp, which can be used to occlude tubing in case it is required to stop fluid flow.
- The IVAC® 597 Volumetric Pump is a positive pressure pump, which should use infusion sets fitted with luer lock fittings or equivalent locking connectors.
- To infuse from a burette, close the roller clamp above the burette and open the clamp on the vent on top of the burette.
- Discard infusion set if the packaging is not intact or the protector cap is detached. Ensure sets are not kinked as this may occlude the tubing.

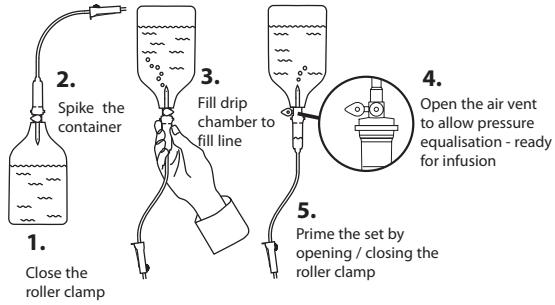
Using Collapsible bags, Glass Bottles & Semi Rigid containers

- It is recommended that the air vent be opened on the IVAC® 597 Volumetric Pump set if using glass bottles or semi-rigid containers, to reduce the partial vacuum formed as the fluid is infused from the container. This action will ensure the pump can maintain volumetric accuracy whilst the container empties. The action of opening the air vent for semi-rigid containers should take place after the spiking of the container and priming of the drip chamber.

Steps for the Collapsible bags

Follow steps 1 to 3 as shown for the semi-rigid containers, however **do not** open vent as in step 4, but prime the set as per step 5. Ensure the bag outlet is fully pierced before filling the drip chamber.

Steps for Semi-rigid containers



Operating Environment

- When using any infusion pump in conjunction with other pumps or devices requiring vascular access, extra care is advised. Adverse delivery of medication or fluids can be caused by the substantial variation in pressures created within the fluid channels of such pumps. Typical examples of those pumps are used during dialysis, bypass or cardiac assist applications.
- The pump is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
- This pump is not intended to be used in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

Operating Pressure

- The pumping pressure alarm system is not designed to provide protection against, or detection of, extravasation or tissuing complications which can occur.

Alarm Conditions

- Several alarm conditions detected by this pump will stop the infusion and generate visual and audible alarms. Users must perform regular checks to ensure that the infusion is progressing correctly and no alarms are operating.

Electromagnetic Compatibility and Interference

- This pump is protected against the effects of external interference, including high energy radio frequency emissions, magnetic fields and electrostatic discharge (for example, as generated by electrosurgical and cauterising equipment, large motors, portable radios, cellular telephones etc.) and is designed to remain safe when unreasonable levels of interference are encountered.
- In some circumstances the pump may be affected by an electrostatic discharge through air at levels close to or above 15kv; or by radio frequency radiation close to or above 10v/m. If the pump is affected by this external interference the pump will remain in a safe mode; the pump will duly stop the infusion and alert the user by generating a combination of visual and audible alarms. Should any encountered alarm condition persist even after user intervention, it is recommended to replace that particular pump and quarantine the pump for the attention of appropriately trained technical personnel.
- This pump is a CISPR 11 Group 1 Class A device and uses RF energy only for its internal function in the normal product offering. Therefore, its RF emissions are very low and are not likely to cause any interference with the nearby electronic equipment. However, this pump emits a certain level of electromagnetic radiation which is within the levels specified by IEC/EN60601-2-24 and IEC/EN60601-1-2. If the pump interacts with other equipment, measures should be taken to minimise the effects, for instance by repositioning or relocation.

Earth Conductor

- The IVAC® 597 Volumetric Pump is a Class I device, therefore must be earthed when connected to an AC power supply.
- This pump also has an internal power source.
- When connected to an external power source, a three-wire (Live, Neutral, Earth) supply must be used. If the integrity of the external protective conductor on the AC power cable has been compromised, the pump should be disconnected from the AC power source and operated utilising the internal battery.

Hazards

- An explosion hazard exists if the pump is used in the presence of flammable anaesthetics. Exercise care to locate the pump away from any such hazardous sources.

- Dangerous Voltage: An electrical shock hazard exists if the pump's casing is opened or removed. Refer all servicing to qualified service personnel.

- If this pump is dropped, subjected to excessive moisture, fluid spillage, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by a qualified service engineer. When transporting or storing the pump, use original packaging where possible, and adhere to temperature, humidity and pressure ranges stated in the Specifications section and on the outer packaging.
- If this pump behaves abnormally, remove from service and contact a qualified service engineer.

Latex Content

- The IVAC® 597 Volumetric Pump does not contain any latex.

Getting Started

Before operating the pump read this Directions For Use (DFU) manual carefully.

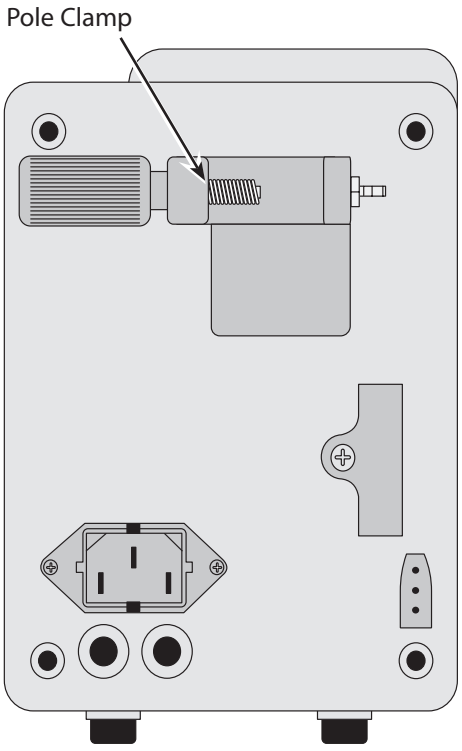
Initial Set Up

1. Check that the pump is complete, undamaged and that the voltage rating specified on the label is compatible with your AC power supply.
2. Items supplied are :
   - **IVAC® 597 Volumetric Pump**
   - **Directions For Use (CD)**
   - **AC Power Cable (as requested)**
   - **Protective Packaging**
3. Connect the pump to the AC power supply for at least **6** hours to ensure that the internal battery is charged (verify that the AC Mains indicator is lit).

The pump will automatically operate from its internal battery if the pump is switched on without being connected to the power supply.
Should the pump fail to perform correctly, replace in its original protective packaging, where possible and contact a qualified service engineer for investigation.

Pole Clamp Installation

A pole clamp is fitted to the rear of the pump and will provide secure fixing to vertical I.V. poles of a diameter between 12 and 26 mm.



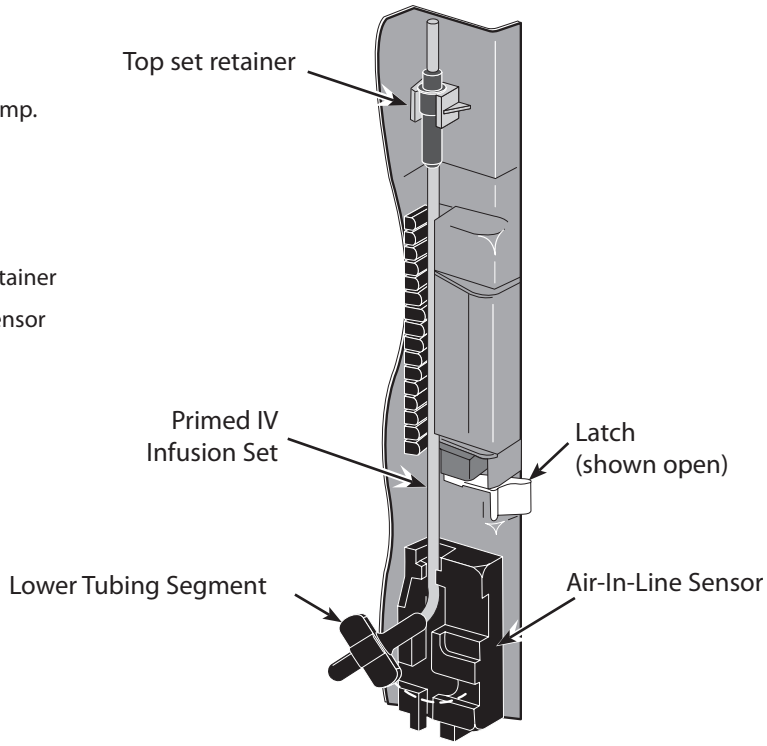
1. Unscrew the clamp to leave enough room for the size of the pole.
2. Place pump around pole and tighten screw until the clamp is secured to the pole.

Never mount the pump such that the infusion stand becomes top heavy or unstable.

Getting Started (Continued) - Loading an Infusion Set

Ensure the appropriate infusion set for the fluid/drug to be infused has been selected.
Follow the instructions supplied with the individual infusion set.
Only use IVAC® 597 Volumetric Pump infusion sets, (Refer to 'Infusion Sets' section of the DFU)
Position the fluid container to avoid spillage onto the pump.
Ensure that the tubing is inserted completely into the top set retainer through to the tubing guide avoiding any slack.

1. Prime the IV infusion set ***slowly*** and close the roller clamp.
2. Open the door.
3. Load the primed IV infusion set:
   - Open the latch
   - Load the upper tubing segment into the top set retainer
   - Insert lower tubing segment into the Air-In-Line Sensor
   - Close the latch, ensuring the set is enclosed
4. Close the door.
5. Open the roller clamp. ***Ensure no fluid flows***.



Getting Started (Continued) - Starting the Infusion

PRIME AND LOAD THE SET (Refer to 'Loading an Infusion Set')

1. Ensure the pump is connected to an AC power supply (also operates from battery).
2. Connect flow sensor, if required. (See 'Flow Sensor Operation')
3. Press the **ON/OFF** switch to power on the pump in Primary mode. The pump will power up and the pri and ml/hr indicators will light. The display will show **pri** and **rate** alternating with the rate value.
4. Use the chevron switches (⩓, ∧, ⩔ and ∨) to set or change the infusion rate.
5. To read the total infused volume press and hold the **READ VOL** switch. To clear the total infused volume, press and hold the **CLEAR VOL** switch until the display reads **0000** (four zeros).
6. Press **VOL TO BE INF** if required. The VTBI and ml indicators will light. The display will show **VTBI** and **PRI** alternating with the current VTBI value. When operating the pump without a flow sensor, a VTBI must be entered. This value is independent of any volume already infused. If the VTBI is at **0000** and the **RUN/HOLD** switch is pressed, the prompt **SET VTBI** will be displayed.

   When operating the pump with a flow sensor, and a VTBI is not desired, press the ⩔ switch until **OFF** is displayed.
7. Use the chevron switches (⩓, ∧, ⩔ and ∨) to set VTBI.
8. Connect the infusion set to the patient access device.
9. Press **RUN/HOLD** to start infusion. The run indicator will appear when the pump mechanism begins to operate.

Changing the infusion rate

1. Press the **RUN/HOLD** switch to place the pump on hold.
2. Adjust rate by using the chevron switches.
3. Restart the pump by pressing the **RUN/HOLD** keys.

Clearing total volume infused

1. Press the **RUN/HOLD** switch to place the pump on hold.
2. Press and hold **CLEAR VOL** for 2 seconds, until display shows **0000**.
3. Restart the pump by pressing the **RUN/HOLD** keys.

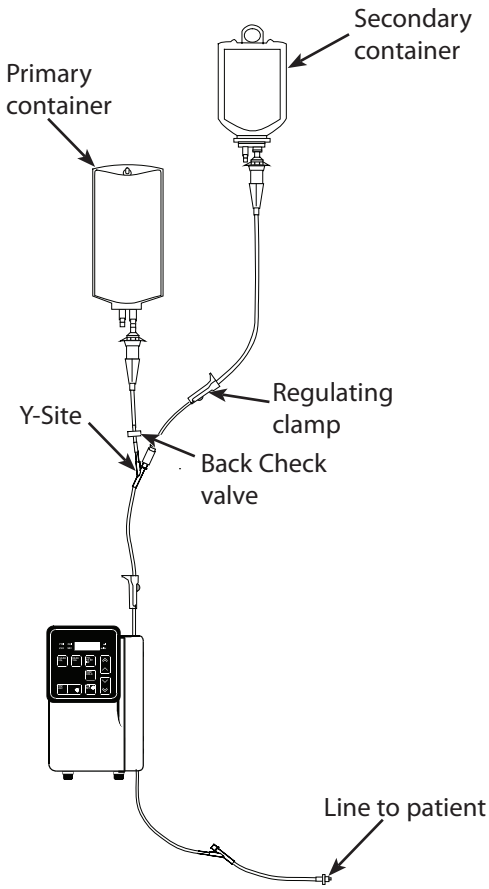
Changing the Volume To Be Infused

1. Press the **RUN/HOLD** switch to place the pump on hold.
2. Press the **VOL TO BE INF** switch.
3. Set new volume by pressing the chevron switches. **OFF** can also be selected when a flow sensor is in use, see Notes below.
4. Restart the pump by pressing the **RUN/HOLD** switch.

Notes:

1) Without a flow sensor in use, a VTBI value *must* be entered, otherwise, the pump displays **VTBI** when the pump is restarted.
2) With a flow sensor in use, a VTBI value isn't required and **OFF** can be selected if required.

1. Load the primed set. See 'Loading the Infusion Set' for instructions.
2. Prepare the secondary infusion using a secondary solution container and the IVAC® "59" Series check valve primary set; lower the primary container. See illustration right.
   - Prime the secondary infusion set in accordance with the set *Directions for Use*
   - Attach secondary infusion set to the upper Y-site of the primary infusion set
   - Fully open the regulating clamp on the secondary infusion set.
3. Press the **ON/OFF** switch to power on the pump. Pump always starts up in PRIMARY mode.
4. Use the chevron switches to set the primary rate.
5. Press **VOL TO BE INF** if required.
6. Set primary VTBI if required.
7. Press and hold the **PRI/SEC** switch for one second. Pump will sound low and high tone and switch to SECONDARY mode.
8. Use the chevron switches to set the secondary rate.
9. Press the **VOL TO BE INF** switch.
10. Set secondary VTBI by using the chevron switches.
11. Press **RUN/HOLD** to start secondary infusion.



Secondary Infusion Preparation

WARNING:

Secondary infusion applications using a check valve set must have a VTBI setting equal to the volume in the secondary container; this will require consideration of such variables as factory overfill, medication additions, etc.

Underestimating the volume will cause remaining secondary solution to be infused at the primary rate; overestimating will result in primary solution being infused at the secondary rate.

When using a flow sensor it must be on the primary infusion set. Correct placement of a flow sensor is essential for proper operation.

Basic Features

KVO (Keep Vein Open) Rate

When using a flow sensor and the solution container empties, the pump will alarm and **FLO** will be displayed.
When not using a flow sensor and the pump has counted down to zero from the preset volume-to-be-infused value, it automatically switches to a 5 ml/h KVO rate, (or current rate, whichever is less), lights the KVO indicator, and produces two audible beeps every 5 seconds.

1. To exit the KVO mode, press the **RUN/HOLD** switch to place the pump on hold.
2. Press the **VTBI** switch. Set the VTBI to a value greater than zero.
3. Press **RUN/HOLD** to continue pump operation.

Changing the Infusion Set

1. Press **RUN/HOLD** switch to place the pump on hold.
2. Close in-line clamp and ensure the access to the patient is isolated.
3. Disconnect the infusion set from the patient.
4. Open pump door and remove infusion set from the pump and discard the set and fluid container according to hospital protocol.
5. Prepare the new infusion set, load infusion set into pump and close the door, see "Loading the Infusion Set".
6. Restart infusion, see "Getting Started".

When changing the infusion set or the fluid container use aseptic technique according to hospital protocol.
It is recommended that infusion sets are changed in accordance with the Directions For Use.
Carefully read the Directions For Use supplied with the infusion set prior to use.
The set change interval is 24 hours.

Changing the Fluid Container

1. Press **RUN/HOLD** switch to place the pump on hold.
2. Remove bag spike on infusion set from empty / used container. Discard empty / used container according to hospital protocol.
3. Insert spike into new container.
4. Squeeze the drip chamber approximately half full or up to fill line (if the drip chamber is marked) with fluid.
5. Restart infusion, see "Getting Started".

When changing the infusion set or the fluid container use aseptic technique according to hospital protocol.
It is recommended that infusion sets are changed in accordance with the Directions For Use.
Carefully read the Directions For Use supplied with the infusion set prior to use.

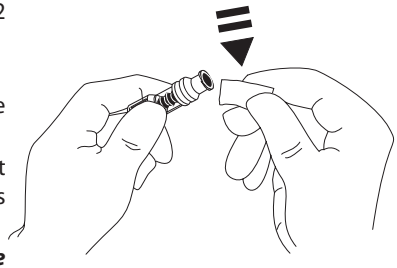
SmartSite® Needle-Free System Instructions

SmartSite® Needle-Free Valve is designed to permit safe gravity flow and automated flow, injection and aspiration of fluids without the use of needles by utilising luer lock and luer slip connectors.

Precautions:
Discard if packaging is not intact or protector caps are unattached.
If Needle-Free Valve is accessed by a needle in an emergency the valve will be damaged causing leakage. Replace Needle-Free Valve immediately.
Needle-Free Valve contraindicated for blunt cannula system.
DO NOT leave slip luer syringes unattended.

DIRECTIONS - Use Aseptic Technique

1. Prior to every access, swab top of Needle-Free Valve port with 70% Isopropyl alcohol (1-2 seconds) and allow to dry (approximately 30 seconds).
   NOTE: Dry time is dependent on temperature, humidity, ventilation of the area.
2. Prime valve port. If applicable, attach syringe to Needle-Free Valve port and aspirate minuscule air bubbles.
3. Replace every 72 hours for stand alone valves. However, if the valve is part of the set, then the set change interval is as per the complete set or 100 activations which ever occurs first. For infusions of blood, blood products or lipid emulsions replace infusion set every 24 hours.



NOTE: During use of Needle-Free Valve port, fluid may be observed between the housing and blue piston. This fluid does not enter the fluid path and requires no action. For product questions or needle-free valve educational materials contact your Cardinal Health, Alaris® Products representative. The Center for Disease Control, Intravenous Nurses Society (USA) and other organizations publish guidelines useful in developing facility guidelines. Consult facility protocols.

Alarm and Display Messages

If the pump sounds an alarm, note the alarm message and press the **RUN/HOLD** switch to place the pump on hold and silence the alarm.
Use the following guide to eliminate the cause of the alarm.
After correcting the condition, press the **RUN/HOLD** switch again to restart the infusion.

Displays Flashing Message with Audible Alarm

Display	Cause	Action
FLO	Upstream Occlusion	Check the tubing, clamp and container for probable causes and correct. (Repeated alarms may indicate pump mechanism requires cleaning. Refer to the CLEANING section of this DFU.)
FLO.1	Too few or no drops	The flow sensor has detected no or insufficient flow. Check tubing, clamp, container and flow sensor for probable causes and correct.
FLO.2	Drip chamber problem. Flow sensor disconnected while pump in operation.	Abnormal drops detected. Drip chamber fogged or overfilled. Shake drip chamber to clear sidewalls; reduce fluid level in drip chamber. Plug flow sensor into connector on rear of instrument. Possible faulty flow sensor.
FLO.3	Too many drops.	Flow detected in excess of the set rate. Flow detected while the pump is on hold or in the start up mode. Check that the set tubing is completely installed in the mechanism, that the mechanism pinches off the tubing and that the drip chamber is not swinging excessively or overfilled.
OCCL	Downstream occlusion.	Check for kinked tubing, clogged filter. (Repeated alarms may indicate pump mechanism requires cleaning. Refer to the CLEANING section of this DFU.)
RELOAD	Set adapter improperly loaded into air detector.	Reload adapter into air detector. Press firmly until flush.
RELOAD - - - - AIR	Air detector senses air in tubing, - or - Set adapter improperly loaded into air detector.	Ensure air detector is clean. Reload set adapter into air detector. Press firmly until flush.
AIR	Air detector senses air in tubing or set adapter dislodged from air detector.	Remove air according to hospital protocol. Ensure air detector is clean.
DOOR	Door opened during infusion or upon entering run mode.	Check set for proper installation. Close door and re-start pump.
BATT	Battery has insufficient charge to operate pump	Plug power cord into an AC outlet. Pump will be operable immediately.
HOLD	Two minutes have elapsed since pump was placed on hold or into start-up mode, or a switch may be stuck. If the pump is in start-up mode and on battery power, it will automatically power-off if left in this alarm for 3 minutes.	Press RUN/HOLD switch once to silence alarm, and again to restart pump. If switch is stuck, contact qualified service personnel.
KVO005 or less (two beeps)	Pump is in KVO mode.	Set the VTBI value to a non-zero value.
ERR (followed by a letter or number)	Possible pump malfunction.	Cycle power off, then on. If problem persists, do not use pump. Contact qualified service personnel.
ERR n	Pump mechanism requires cleaning.	Refer to the CLEANING section of this DFU.
Momentary display that disappears shortly after power-up.	Pump has automatically shut off due to low battery charge.	Plug the power cord into an AC outlet. The pump will be operable after several seconds.

Alarm and Display Messages

Alternating Messages

Display	Cause	Action
BAT. (alternating with rate display, pump continues to run)	Low battery; battery has about 1 hour or less of useable charge remaining.	Plug the power cord into an AC outlet.
PRI (alternating with rate value)	Pump is infusing in primary mode at the displayed rate. This is not an alarm condition.	
SEC (alternating with rate value)	Pump is infusing in secondary mode at the displayed rate. This is not an alarm condition.	
PRI HOLD or SEC HOLD (alternating with rate value)	Pump has been placed on hold. This is not an alarm condition.	Press **RUN/HOLD** switch once to restart infusion.
PRI RATE or SEC RATE (alternating with rate value)	Pump is in rate setting mode. This is not an alarm condition.	Press **RUN/HOLD** or **VOL TO BE INF** switch to advance to VTBI setting mode.
PRI VTBI or SEC VTBI (alternating with VTBI value)	Pump is in VTBI setting mode. This is not an alarm condition.	Press **RUN/HOLD** switch once to start infusion.

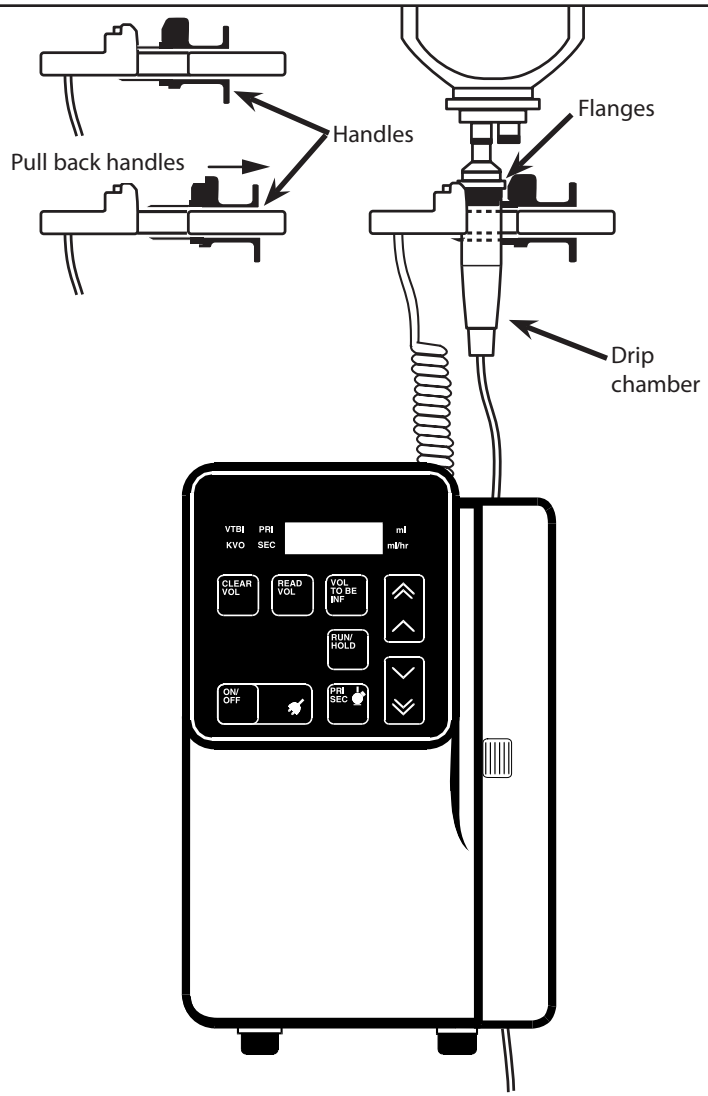
Prompts

Display	Cause	Action
SET VTBI	VTBI value is at zero.	Set the VTBI value to a non-zero value or operate the pump with a flow sensor and set VTBI to OFF.
SET RATE	Rate set to zero.	Enter a non-zero rate.
CRIS	Pump is configured for CRIS operation.	Verify that CRIS is displayed when turning the pump on and again when entering the secondary mode.
PRI VTBI	Pump is configured for CRIS operation. The secondary VTBI value just entered is higher than the currently set primary VTBI. The pump will not start the infusion when the RUN/HOLD switch is pressed.	Return to primary mode and readjust the primary VTBI to a value equal to or higher than the secondary VTBI.

Flow Sensor Operation (Optional)

The flow sensor automatically detects drops falling in the drip chamber. The flow sensor will cause the pump to alarm if a significant deviation from the infusion rate occurs. The flow sensor will also be able to detect empty containers. For this reason we recommend use of a flow sensor wherever possible.

IVAC® Flow Sensor Model 192



1. Plug the flow sensor into the flow sensor interface located on the top rear part of the pump.
2. Attach the IVAC® Flow Sensor Model 192 to the drip chamber of the infusion set, by pulling back the handles. Refer to the illustration above.
3. Proceed with load, priming, and set-up instructions as described in section "Getting Started".

NOTE: Ensure drip chamber is half full and upright.

Always attach the flow sensor before you start an infusion .
Avoid using the flow sensor in direct sunlight.
Always ensure lens is clean.

Specifications

Electrical Protection

Class I, Type CF

Electrical/Mechanical Safety

Complies with IEC/EN60601-1 and IEC/EN60601-2-24.

Electro Magnetic Compatibility (EMC)

Complies with IEC/EN60601-1-2 and IEC/EN60601-2-24.

Electrical Safety

IEC/EN60601-1;

Earth Leakage Current (Normal Condition) Maximum 100µA rms (ungrounded) at 220V rms

Classification - Continuous mode of operation, Portable Equipment

AC Power Supply -

220 to 240V AC; 50/60 Hz; 0.07A; 3-wire grounded system.

Fuse Type -

2 X T63 mA 250V

Dimensions -

133mm (w) x 193mm (h) x 184mm (d). Weight: approx. 2.7kg (excluding power cable).

Protection against fluid ingress -

IPX1 - Protected against vertically falling drops of water.

Environmental Specifications

Condition	Operating	Transport & Storage
Temperature	+10°C to +40°C	-40°C to +70°C
Humidity	30% to 75% non-condensing	0% to 100%
Atmospheric Pressure	700hPa - 1060 hPa	500hPa - 1060hPa

System Accuracy:

±5% with a 1.96 standard deviation under specified conditions.
Note: Accuracy specified under the following conditions:
Head height: 30"/76.2cm,
Test solution: distilled water,
Environmental: ambient temperature,
Back pressure: 20 gauge needle,
Infusion Set: Model 59073 (59073 has been superseded by G59073, which is identical to the previous infusion set)

Starting the Infusion / Set-up

Infusion Parameter	Range
Infusion Rate	1 - 999ml/h in steps of 1ml/h
VTBI	(0 - OFF), 1 - 9999ml in 1ml increments
VI (Total)	0 - 9999ml
KVO rate	5 ml/h or current set rate if less than 5 ml/h in primary operation

BATTERY SPECIFICATIONS -
Rechargeable Sealed Lead Acid. Automatically charges when the pump is connected to AC power.

Battery Life - 6 hours @ 125ml/h

Battery Charging - 24 hours.

Alarm Conditions -

Alarm conditions cause the pump to display specific alarm messages, sound an audible alarm, and except for the low battery and KVO mode alerts, cease operation. Alarm and display messages include: FLO, door, hold, bat., batt., OCCL, RELOAD, Air and Err.
(See the ALARMS AND DISPLAY MESSAGES section of this DFU for message descriptions.)

Memory Retention -

At 25°C, the electronic memory of the pump will be retained for at least 6 months when not powered up

Air Sensor - Integral Ultrasonic Sensor.

Maximum time for activation of occlusion alarm:

Time to alarm at 1ml/h is nominally 35 minutes
Time to alarm at 100ml/h is nominally 0.31 minutes

Air in Line Accuracy:

100 µl ±50 µl

Maximum Occlusion Alarm Pressure:

11 psi (569 mmHg); Nominal: 6 to 8 psi

Post Occlusion Bolus:

Bolus volume generated at 1 ml/h when the occlusion alarm threshold is reached 0.5 ml
Bolus volume generated at 100 ml/h when the occlusion alarm threshold is reached <0.5 ml

Critical Volume

25 ml at 999 ml/h is maximum incremental volume which can occur in case of single point failure

Maintenance

Routine Maintenance Procedures

To ensure that this pump remains in good operating condition, it is important to keep it clean and carry out the routine maintenance procedures described below. All servicing should only be performed by a qualified service engineer with reference to the Technical Service Manual (TSM). Circuit diagrams and components parts lists and all other servicing information which will assist the qualified service engineer in performing repair of the parts designated as repairable are available upon request from Cardinal Health.

If the pump is dropped, damaged, subjected to excessive moisture or high temperature, immediately take it out of service for examination by a qualified service engineer.

All preventative and corrective maintenance and all such activities shall be performed at a compliant work place in accordance with the information supplied. Cardinal Health, Alaris® Products will not be responsible should any of these actions be performed outside the instructions or information supplied by Cardinal Health.

Refer to the Technical Service Manual for the access code for technical service.

INTERVAL	ROUTINE MAINTENANCE PROCEDURE
As per Hospital policy.	Thoroughly clean external surfaces of the pump before and after prolonged period of storage.
At least once per year (Refer to TSM for identification of parts)	1. Inspect AC power supply plug and cable for damage. 2. Perform functional tests as outlined in the Technical Service Manual. 3. Operate the pump on battery power until the battery low alarm then charge the battery to confirm battery operation and charging. 4. Inspect mechanism for damage or excessive wear. Clean and lubricate the mechanism as outlined in the Technical Service Manual.

Please refer to Technical Service Manual for calibration procedures. The units of measurement used in the calibration procedure are standard SI (The International System of Units) units.

Replacing the Mains Fuses

If the pump continually illuminates the battery symbol and the AC power indicator light does not illuminate when the pump is connected to the AC power supply and switched ON, either the power supply fuse in the AC plug, if fitted, or the internal fuses may have blown.

First check the power supply fuse in the AC mains plug, if fitted. If the AC power indicator light does not illuminate remove the pump from service. It is recommended that the AC power fuses are only replaced by a qualified service engineer.

The fuses in the pump should only be replaced by a qualified service engineer. For further information regarding the replacement of fuses refer to the Technical Service Manual.

If the fuses continue to blow, an electrical fault may have occurred and the pump and power supply should be checked out by a qualified service engineer.

Battery Operation

The internal rechargeable battery allows continued operation when the AC power is unavailable, for example during patient transfer or AC power failure. A fully charged battery will provide a minimum of 6 hours of operation at 125ml/h infusion rate. When connected to the AC power supply for 24 hours, (whether the pump is in use or not) a battery pack will be fully charged.

The battery is maintenance free, sealed Lead Acid and requires no routine servicing. However, to achieve optimum operation, ensure that the battery is fully recharged after full discharge, before storage, and at regular 3 month intervals during storage.

Charge retention will eventually degrade. Where retention is critical the internal battery should be replaced every 3 years.

It is recommended that only a qualified service engineer replaces the battery. For further information regarding the replacement of batteries refer to the Technical Service Manual.

Test Routines

The test routines are designed to allow confirmation of many of the pump functions, defaults and calibrations without requiring internal inspection. They do not represent a full calibration check.

See the Technical Service Manual for a complete list of the test procedures, access codes and calibration procedures.

Cleaning and Storage

Cleaning the pump: -
Before the transfer of the pump to a new patient and periodically during the use, clean the pump by wiping over with a lint-free cloth lightly dampened with warm water and a standard disinfectant / detergent solution.

Before cleaning always switch off and disconnect from the AC power supply. Do not allow liquid to enter the casing and avoid excess fluid build up on the pump.

Do not use aggressive cleaning agents as these may damage the exterior surface of the pump.
Do not steam autoclave, ethylene oxide sterilise or immerse this pump in any fluid.

Recommended cleaners are:

Brand	**Concentration**
Hibiscrub	20% (v/v)
Virkon	1% (w/v)

Do not use the following disinfectant types:

- NaDcc (such as PRESEPT)
- Hypochlorites (such as CHLORASOL)
- Aldehydes (such as CIDEX)
- Cationic Surfactants (such as Benzalkonium Chloride)
- Iodine (such as Betadine)
- Concentrated Isopropyl alcohol based cleaners will degrade plastic parts.

Storing the pump: -
If the pump is to be stored for an extended period it should be first cleaned and the internal battery fully charged. Store in a clean, dry atmosphere at room temperature and, if available, employ the original packaging for protection.
Once every 3 months during storage, carry out functional tests as described in the technical service manual and ensure that the internal battery is fully charged.

Cleaning and storing the infusion set: -
The infusion set is a disposable single use item and should be discarded after use according to hospital protocol.

Cleaning the Flow Sensor: -
Before the transfer of the flow sensor to a new infusion set and periodically during use, clean the flow sensor by wiping over with a lint-free cloth lightly dampened with warm water and a standard disinfectant / detergent solution. Ensure the connector does not get wet. Dry flow sensor before use.
To aid cleaning of flow sensors which have been heavily soiled, contaminated or if the handle operation is not free moving, then the flow sensor may be immersed and soaked in clean soapy water (see). The inside of the spring mechanism can be cleaned by activating it whilst submerged in the water.
After cleaning, the sensor should be allowed to dry fully prior to use.

The plug of the flow sensor must not be immersed in water as damage will occur.

Disposal

Information on Disposal for Users of Waste Electrical & Electronic Equipment

This symbol on the product and/or accompanying documents means that used electrical and electronic products should not be mixed with household waste.

If you wish to discard electrical and electronic equipment, please contact your Cardinal Health affiliate office or distributor for further information.

Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

Information on Disposal in Countries outside the European Union

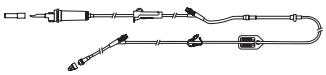
This symbol is only valid in the European Union. The product should be disposed of taking environmental factors into consideration. To ensure no risk or hazard, remove the internal rechargeable battery and the Nickel Metal Hydride battery from the control board and dispose of as outlined by the local country regulations. All other components can be safely disposed of as per local regulations.

Infusion Sets

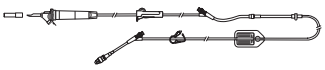
The IVAC® 597 Volumetric Pump uses standard, single-use, disposable infusion sets. The user is responsible for verifying the suitability of a product used, if it is not recommended by Cardinal Health.

Standard infusion sets

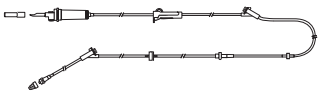
G59033E
- 2 SmartSite® Needle-Free Valve Ports
- 15 Micron Filter & 0.2 Micron In Line Filter
- Length: 265cm



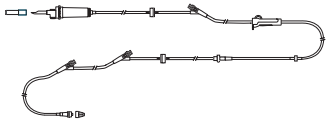
G59123E
- 2 SmartSite® Needle-Free Valve Ports
- 15 Micron Filter & 1.2 Micron In Line Filter
- Length: 260cm



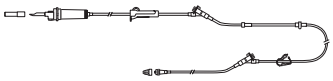
G59021
- No Filter
- Length: 267cm



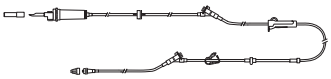
G59027E
- 3 SmartSite® Needle-Free Valve Ports
- No Filter
- Length: 260cm



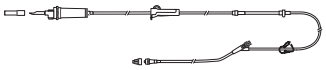
G59073
- No Filter
- Length: 260cm



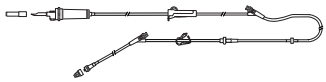
G59093
- 15 Micron Filter
- Length: 260cm



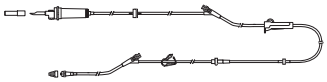
G59173E
- 1 SmartSite® Needle-Free Valve Port
- No Filter
- Length: 260cm



G59273E
- 2 SmartSite® Needle-Free Valve Ports
- No Filter
- Length: 260cm



G59293E
- 2 SmartSite® Needle-Free Valve Ports
- No Filter
- Length: 260cm

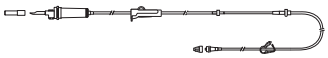


G59593
- 15 Micron Filter
- Length: 270cm

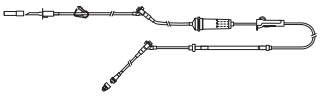
G59693E
- 1 SmartSite® Needle-Free Valve Port
- 15 Micron Filter
- Length: 255cm

G59793E
- 2 SmartSite® Needle-Free Valve Ports
- 15 Micron Filter
- Length: 255cm

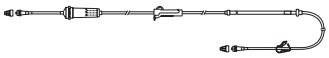
G59903
- 15 Micron Filter
- Length: 250cm



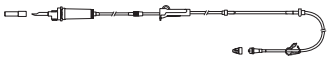
G59394
- 15 Micron Filter
- Length: 270cm



G59016
- 15 Micron Filter
- Length: 275cm

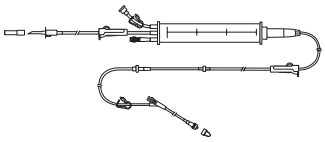


G59953
- 15 Micron Filter
- Low Sorbing Infusion Set
- Length: 260cm



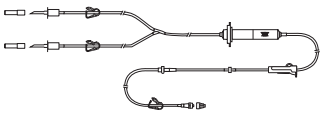
G59643
- 15 Micron Filter
- Opaque white PVC Infusion Set
- Length: 250cm

G59103E
- 2 SmartSite® Needle-Free Valve Ports
- 1 Burette (150ml)
- Length: 270cm

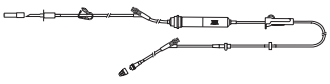


Blood Transfusion sets

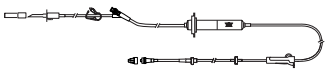
G59024
- 200 Micron Filter
- Length: 295cm



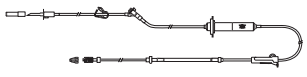
G59393E
- 2 SmartSite® Needle-Free Valve Ports
- 200 Micron Filter
- Length: 270cm



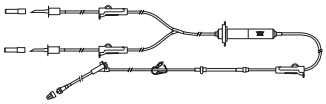
G59893E
- 1 SmartSite® Needle-Free Valve Port
- 200 Micron Filter
- Length: 255cm



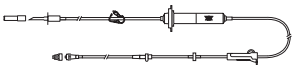
G59894
- 200 Micron Filter
- Length: 255cm



G59980
- 200 Micron Filter
- Length: 250cm



G59895
- 200 Micron Filter
- Length: 255cm



It is recommended that infusion sets are changed according to the instructions in the 'Changing the Infusion Set' section. Carefully read the Directions For Use supplied with the infusion set prior to use.

Please note these drawings are not to scale

Trumpet and Flow Rate Curves

In this pump, as with all infusion systems, the action of the pumping mechanism and variations cause short-term fluctuations in rate accuracy.

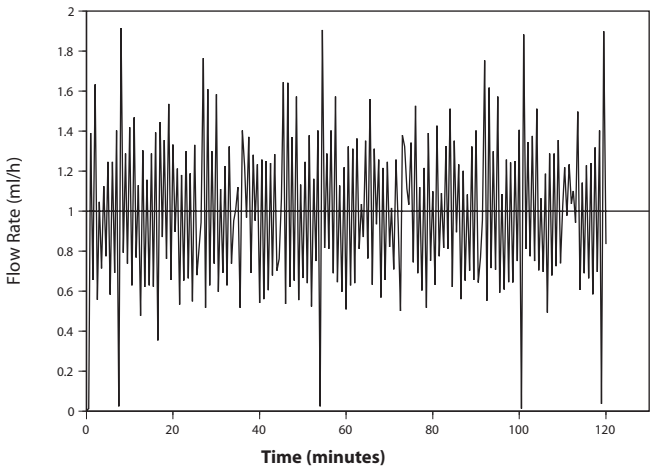
The following curves show typical performance of the system in two ways: 1) the accuracy of fluid delivery over various time periods is measured (trumpet curves), and 2) the delay in onset of fluid flow when infusion commences (start-up curves).

Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or 'observation windows', not continuous data versus operating time. Over long observation windows, short term fluctuations have little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short term fluctuations have greater effects as represented by the "mouth" of the trumpet.

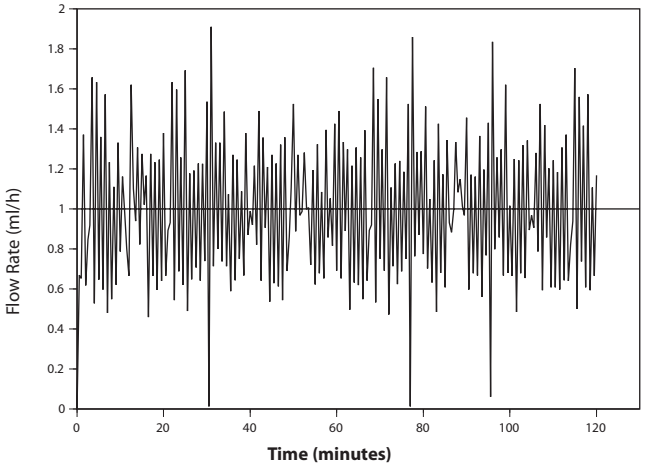
Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short term fluctuations in rate accuracy may have clinical impact depending on the half-life of the drug being infused and the degree of inter vascular integration, the clinical effect cannot be determined from the trumpet curves alone.

The start-up curves represent continuous flow versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Tests performed per IEC/EN60601-2-24 standard.

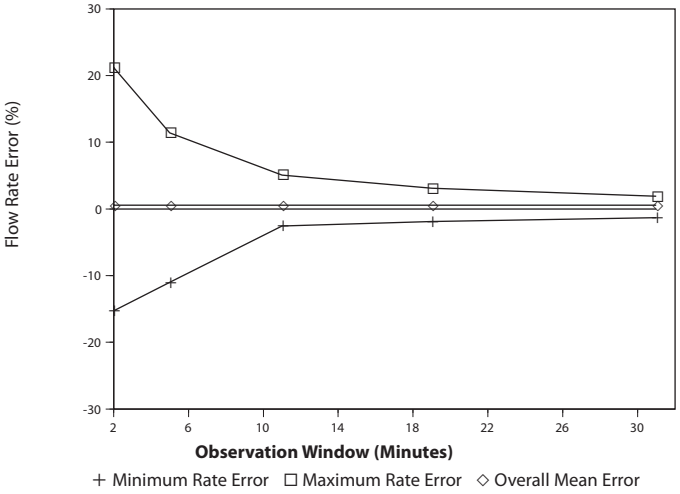
Start-up Graph at 1.0ml/h (Initial Period)



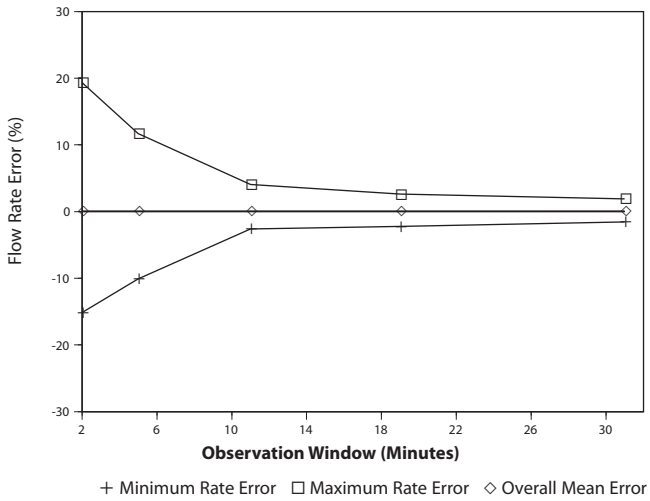
Start-up Graph at 1.0ml/h (24 hour)



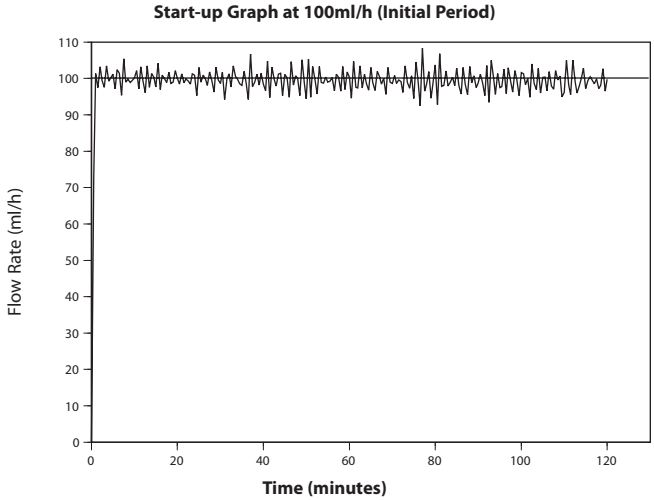
Trumpet Graph at 1.0ml/h (Initial Period)



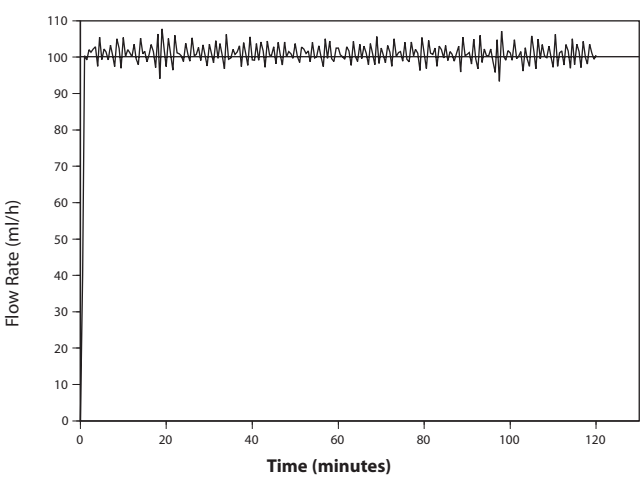
Trumpet Graph at 1.0ml/h (24 Hour)



Start-up Graph at 100ml/h (Initial Period)

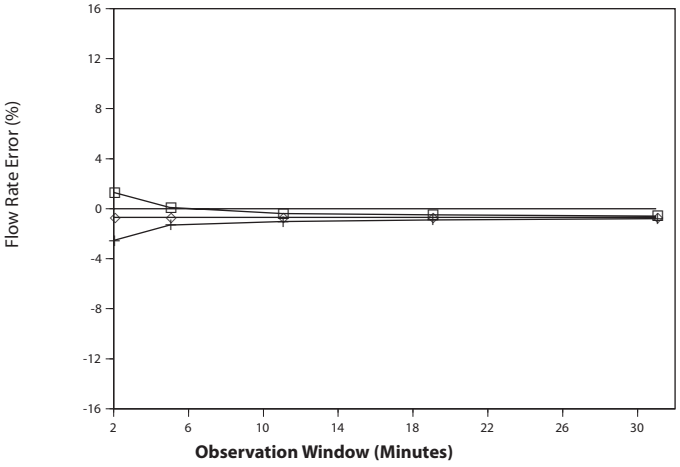


Start-up Graph at 100ml/h (24 hour)



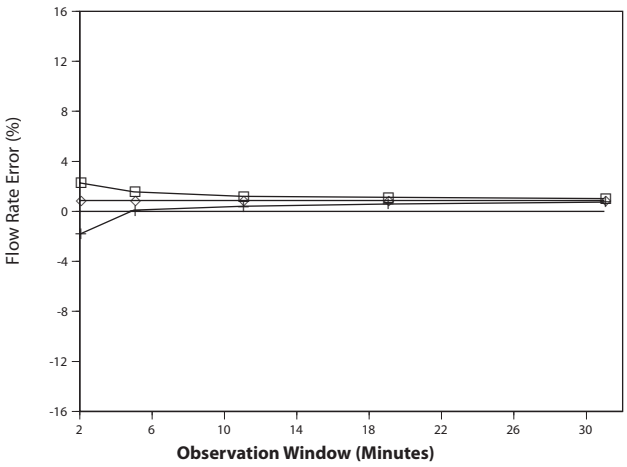
Trumpet & Flow Rate Curves continued

Trumpet Graph at 100ml/h (Initial Period)



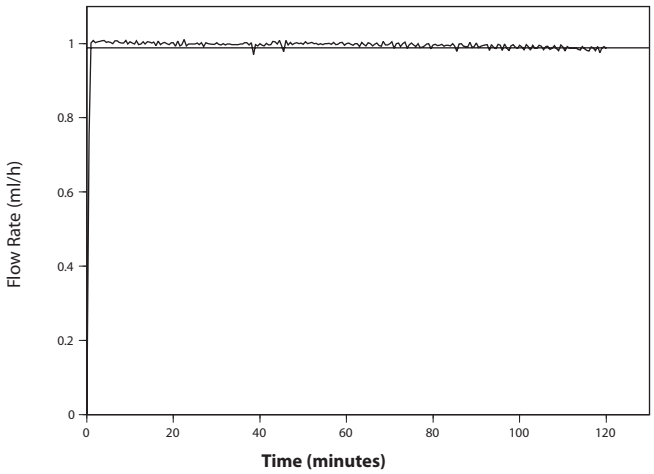
+ Minimum Rate Error ☐ Maximum Rate Error ◇ Overall Mean Error

Trumpet Graph at 100ml/h (24 Hour)

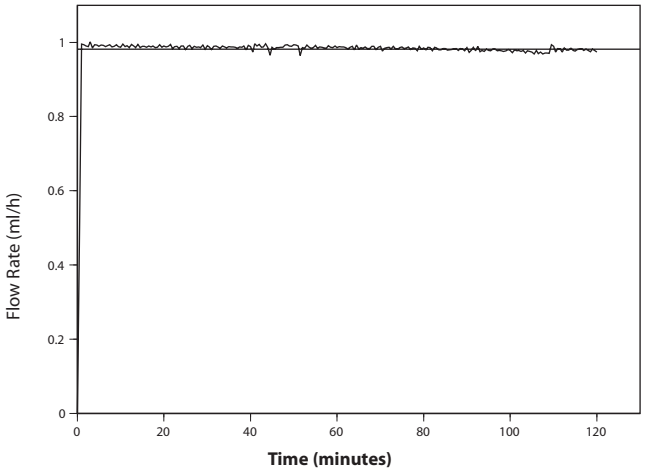


+ Minimum Rate Error ☐ Maximum Rate Error ◇ Overall Mean Error

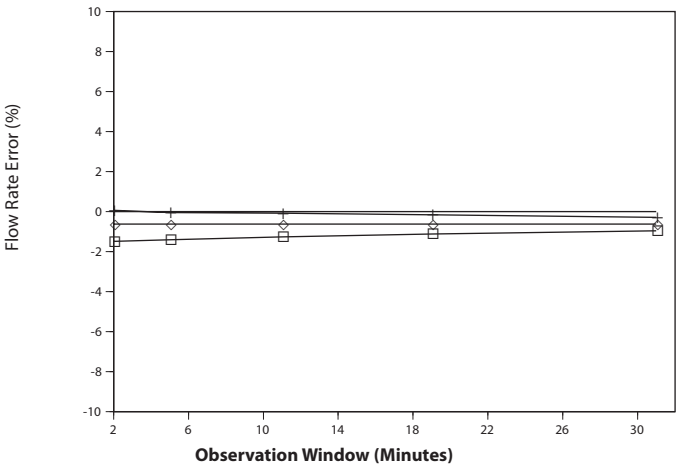
Start-up Graph at 999ml/h (Initial Period)



Start-up Graph at 999ml/h (24 hour)

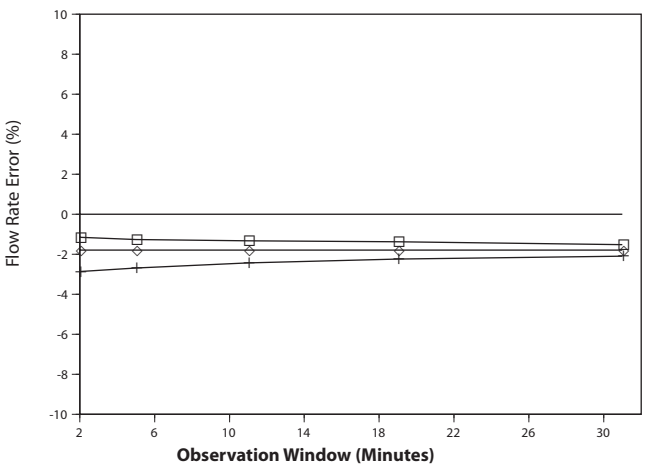


Trumpet Graph at 999ml/h (Initial Period)



+ Minimum Rate Error ☐ Maximum Rate Error ◇ Overall Mean Error

Trumpet Graph at 999ml/h (24 Hour)



+ Minimum Rate Error ☐ Maximum Rate Error ◇ Overall Mean Error

Note: The typical flow rate and trumpet curves are achieved using a recommended infusion set

Alaris® Infusion System

Range of products in the Alaris® Infusion System product family are:

Part Number	Description
80013UN01	Alaris® GS Syringe Pump
80023UN01	Alaris® GH Syringe Pump
80033UND1	Alaris® CC Syringe Pump
80043UN01	Alaris® TIVA Syringe Pump
80053UN01	Alaris® PK Syringe Pump
80263UN01	Alaris® GP Volumetric Pump
80033UND1-G	Alaris® CC Syringe Pump with Guardrails® Safety Software
80023UN01-G	Alaris® GH Syringe Pump with Guardrails® Safety Software
80083UN00-xx*	Alaris® DS Docking Station
80203UNS0xxx*	Alaris® Gateway Workstation

* For Docking Station and Workstation contact local customer services representative to obtain configurations availability and part numbers.

Spare Parts

A comprehensive list of spare parts for this pump is included within the Technical Service Manual.

The Technical Service Manual (1000SM00016) is available in electronic format on the World Wide Web at :-

www.cardinalhealth.com/alaris.

A username and password are required to access our manuals. Please contact a local customer services representative to obtain login details.

Service Contacts

For service contact your local Affiliate Office or Distributor:

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Document History

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1	7330	September 2007

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(B) Each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Cardinal Health to the original purchaser.
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